UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

BARBARA GAYLE, *et al.*,	)	
	)	
Plaintiffs,	)	Case No. 1:19-CV-03451
	)	W.H.P. III, J.
v.	)	
	)	
PFIZER INC., *et al.*	)	
	)	
Defendants.	)	

PFIZER INC.'S REPLY IN SUPPORT OF MOTION FOR JUDGMENT ON THE PLEADINGS AND OPPOSITION TO PLAINTIFFS' REQUEST FOR LEAVE TO AMEND COMPLAINT

INTRODUCTION

Plaintiffs oppose Pfizer's Motion for Judgment on the Pleadings primarily by seeking leave to file a Proposed Amended Complaint ("PAC").[1] Their PAC fails to cure the deficiencies in their original claims. Plaintiffs' request to amend should be denied as futile and their claims should be dismissed with prejudice.

First, Plaintiffs do not even address several defects raised in Pfizer's Motion, and their PAC fails to remedy them. This includes Plaintiffs' failure to plead fraud with particularity and their failure to overcome state law bars to their warranty and consumer fraud claims. Those claims should be dismissed with prejudice.

Second, Plaintiffs' PAC fails to overcome Pfizer's showing that Plaintiffs' claims are preempted to the extent they allege a failure to warn about a risk of diabetes after the FDA-approved label change for Lipitor in February 2012. Their PAC cannot save post-2012 claims from preemption because it does not cure the Complaint's failure to plead any "newly acquired information" not considered by the FDA that could have warranted a different label for Lipitor.

Third, the PAC cannot save any pre-2016 claims from New York's statute of limitations. The PAC still fails even to allege when Plaintiffs were diagnosed with diabetes, much less to plead any particularized allegations supporting fraudulent concealment or statutory tolling.

The Motion for Judgment on the Pleadings thus should be granted.

ARGUMENT

Plaintiffs' request for leave to amend should be denied as futile because the PAC "fails to cure prior deficiencies," *Chunn v. Amtrak*, 916 F.3d 204, 208 (2d Cir. 2019) (quotation mark omitted), and "would not survive another motion to dismiss." *Biswas v. Rouen*, 2019 WL

[1] A redline of the changes in the PAC is attached hereto as Exhibit 1.

5260821, at *5 (S.D.N.Y. Oct. 16, 2019); *accord Zembiec v. Cty. of Monroe*, 468 F. App'x 39, 40 (2d Cir. 2012).

I. PLAINTIFFS FAIL TO ADDRESS SEVERAL GROUNDS FOR DISMISSAL

Plaintiffs do not respond to several of Pfizer's arguments for dismissal. The PAC contains no new allegations, much less sufficient allegations, on several dispositive points. Plaintiffs still have not pleaded fraud with particularity. (Mot. at 15.) They still have not identified any statements by Pfizer that could constitute a warranty or consumer protection violation. (*Id.* at 16–17.)[2] Florida, Minnesota, and Wyoming still do not recognize claims for breach of an implied warranty. (*Id.* at 16.) The NYCPA still does not apply to claims involving prescription drugs. (*Id.* at 17.) And Plaintiffs' claims are still barred by the NYCPA's safe harbor. (*Id.*) Plaintiffs have already had forty-four days to respond to Pfizer's Motion—more than three times longer than the time provided by the local rules—and offer no reason why they should now be permitted to amend or granted additional time to respond to Pfizer's Motion. Because amendment would be futile, dismissal of these claims with prejudice is proper.

II. PLAINTIFFS' POST-FEBRUARY 2012 CLAIMS ARE PREEMPTED

Plaintiffs do not dispute that their claims all are based on a failure-to-warn theory that hinges on the FDA-approved label for Lipitor—that "[the] Lipitor [label] does not include diabetes as a risk of Lipitor usage." (Opp. at 4.) Plaintiffs concede, however, that the FDA has conducted a "comprehensive review" of information relating to Lipitor and other statins (PAC ¶ 45), and, in 2012, the FDA required that Pfizer add new information to the Lipitor label, including a warning about, *inter alia*, "[i]ncreases in HbA1c and fasting serum glucose levels" and information about

[2] Plaintiffs have added a single allegation that, "in the 2007-2008 timeframe," Pfizer ran an advertisement in which an unlicensed medical school graduate "suggest[ed] that he was glad to use Lipitor as a 'doctor.'" (PAC ¶ 157.) Plaintiffs do not allege that they or their doctors saw this advertisement, or otherwise connect the advertisement to their claims.

the SPARCL clinical trial. (Mot. at 4–5.) As the FDA stated in its public announcement of the label change: "Based on clinical trial meta-analyses and epidemiological data from the published literature, ***information concerning an effect of statins on incident diabetes and increases in HbA1c and/or fasting plasma glucose was added*** to statin labels." (Mot., Ex. B (emphasis added)). The FDA thus "reviewed, independently investigated, and commented publicly on the specific issue implicated by Plaintiffs' claims," *Seufert v. Merck Sharp & Dohme Corp.*, 187 F. Supp. 3d 1163, 1177 (S.D. Cal. 2016), and required the inclusion of specific warning language addressing the relevant data on that issue. (*See* Mot. at 4–5.) Plaintiffs acknowledge that, to maintain a claim that Pfizer should have included a different or stronger warning about that issue, they must plead facts showing "newly acquired information" not considered by the FDA that would have enabled Pfizer independently to so change the Lipitor label. (Opp. at 10); *accord, e.g.*, *Gibbons v. Bristol-Myers Squibb Co.*, 919 F.3d 699, 708 (2d Cir. 2019).[3] Nothing in their Complaint or PAC, however, alleges that Pfizer had such information or that such information even exists. Their post-February 2012 claims thus fail.

Plaintiffs' only factual allegation in the PAC purporting to show "newly acquired information" is that between 2012 and 2015, Pfizer allegedly "submitted more than 6,000 adverse event reports to the FDA identifying Diabetes as being an unexpected event for Lipitor." (PAC ¶ 87.) Adverse event reports are anecdotal reports from third parties, and manufacturers forward

[3] *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34, 42–43 (1st Cir. 2015); *McGrath v. Bayer HealthCare Pharma. Inc.*, 393 F. Supp. 3d 161, 170 (E.D.N.Y. 2019); *Goodell v. Bayer Healthcare Pharma. Inc.*, No. 18-10694, 2019 WL 4771136, at *4 (D. Mass. Sept. 30, 2019); *Klein v. Bayer Healthcare Pharma. Inc.*, 2019 WL 3945652, at *5 (D. Nev. Aug. 21, 2019); *Maze v. Bayer Healthcare Pharmaceuticals Inc.*, 2019 WL 1062387, at *2 (E.D. Tenn. Mar. 6, 2019); *Patton v. Forest Labs., Inc.*, 2018 WL 5269239, at *11 (C.D. Cal. Sept. 19, 2018); *McGee v. Boehringer Ingelheim Pharma., Inc.*, 2018 WL 1399237, at *4 (N.D. Ala. Mar. 20, 2018); *Utts v. Bristol-Myer Squibb Co.*, 251 F. Supp. 3d 644, 669 (S.D.N.Y. 2017).

these reports to the FDA if the adverse event occurs near the time the product was used, "whether or not considered drug related." 21 C.F.R. § 314.80(a). The FDA's adverse event reporting system "contain[s] raw information that has not been scientifically or otherwise verified as to cause and effect" and "cannot be used to estimate the incidents of adverse drug reactions, or for comparisons of drug safety." *Haggerty v. Upjohn Co.*, 950 F. Supp. 1160, 1164 (S.D. Fla. 1996); *see also* 21 C.F.R. § 314.80(l). For example, if Pfizer receives a lawsuit alleging that a patient developed diabetes while also taking Lipitor, it will forward that report to the FDA and the report will be included in the adverse event report databases. These allegations about adverse event reports do not constitute "newly acquired information."

First, Plaintiffs' attempt to allege "newly acquired information" through adverse event reports is self-defeating because Plaintiffs specifically allege these adverse event reports were "***submitted . . . to the FDA***." (PAC ¶ 87 (emphasis added).) Information that was before the FDA and that did not prompt the FDA to issue a label change cannot be "***newly acquired*** information," and thus cannot allow Plaintiffs' claims to survive preemption. *Roberto v. Boehringer Ingelheim Pharma., Inc.*, 2019 WL 5068452, at *23 (Conn. Super. Ct. Sept. 11, 2019); *cf. In re Celexa*, 779 F.3d at 42–43; *Maze*, 2019 WL 1062387, at *3; *Dobbs v. Wyeth Pharma.*, 797 F. Supp. 2d 1264, 1272–73 (W.D. Okla. 2011).

Second, Plaintiffs have not alleged that these post-2012 adverse event reports "reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA." *Gibbons*, 919 F.3d at 708; 21 C.F.R. § 314.3(b). Courts have found preemption even where plaintiffs have relied not simply on raw reports that have been considered by the FDA, but also on purportedly new analyses of adverse event reports. Judge Cote dismissed such a complaint as preempted in *Utts v. Bristol-Myer Squibb Co.*, 251 F. Supp. 3d 644 (S.D.N.Y. 2017), *aff'd sub*

nom. Gibbons v. Bristol-Myers Squibb Co., 919 F.3d 699 (2d Cir. 2019). Judge Cote held that preemption applied because the analysis of adverse event reports submitted by the plaintiffs did "not suggest—nor [did] the plaintiffs allege—that the real-world signal data for [the medication] shows a greater severity or frequency of" relevant adverse events than "the clinical data disclosed by the defendants to the FDA." *Id.* at 665; *see also Maze*, 2019 WL 1062387, at *3; *McGee v. Boehringer Ingelheim Pharma., Inc.*, No. 16-2082, 2018 WL 1399237, at *4 (N.D. Ala. Mar. 20, 2018); *Dobbs*, 797 F. Supp. 2d at 1272–74.

Here, Plaintiffs argue only that the reports are sufficient to create a "basis to believe" that Lipitor is capable of causing diabetes sufficient for inclusion in the "Adverse Reactions" section of the labeling. 21 C.F.R. § 201.57(c)(7). The reports show no such thing,[4] but even if they could, that does not make them "newly acquired information." Plaintiffs do not allege—let alone submit any analysis showing—that these post-February 2012 adverse event reports "reveal risks of a different type" or greater "frequency" than the data already considered by the FDA, as they must under *Gibbons*. To the contrary, the public records cited in Pfizer's Motion show that the FDA considered similar data and publications about the exact same "risk" alleged by Plaintiffs—type 2 diabetes—but required warning language about increased blood glucose rather than a warning that Lipitor causes diabetes. Because Plaintiffs have failed to identify "newly acquired information,"

[4] *See, e.g.*, 21 C.F.R. § 314.80(l); *Dobbs v. Wyeth Pharma.*, 797 F. Supp. 2d 1264, 1273 (W.D. Okla. 2011) ("[T]he record reflects that the FDA has not considered individual manufacturers' reports of adverse events sufficiently persuasive to provide 'reasonable evidence of an association' between the drug and the reported adverse consequence."); FDA, Guidance for Industry: Adverse Reactions Section of Labeling for Human Prescription Drug & Biological Products—Content and Format 8 (Jan. 2006), *available at* https://www.fda.gov/media/72139/download ("The definition of adverse reactions does not include all adverse events observed during use of a drug."); *see also Rider v. Sandoz Pharma. Corp.*, 295 F.3d 1194, 1199 (11th Cir. 2002); *Glastetter v. Novartis Pharma. Corp.*, 252 F.3d 986, 990 (8th Cir. 2001); *Soldo v. Sandoz Pharma. Corp.*, 244 F. Supp. 2d 434, 541 (W.D. Pa. 2003); *Haggerty*, 950 F. Supp. at 1164.

they have not alleged facts that can plausibly overcome preemption. *Roberto*, 2019 WL 5068452, at *11 ("[I]f there is no newly acquired information, then the manufacturer is under no duty to change its label and related state failure to warn claims are preempted.").

Instead of answering for their critical lack of allegations of "newly acquired information," Plaintiffs focus on whether the Lipitor label warns of diabetes or whether Pfizer "requested a labeling change adding diabetes to the label." (Opp. at 9–10.) Both are irrelevant absent the essential allegations of "newly acquired information" not considered by the FDA.[5] This deficiency requires dismissal with prejudice of Plaintiffs' post-February 2012 claims.

Nor is there merit to Plaintiffs' alternative request to convert Pfizer's Motion for Judgment on the Pleadings to a motion for summary judgment. (Opp. at 7.) As the *Merck* Court held last term, whether failure-to-warn claims against a manufacturer of a branded prescription medication are preempted is a question of law that may be resolved by the Court, *Merck*, 139 S. Ct. at 1672, and courts in the Second Circuit and elsewhere have repeatedly addressed that question at the pleading stage. (*See* n.3, *supra*.) Here, Plaintiffs do not dispute that the FDA's judicially-noticeable records for Lipitor show "comprehensive review" of the clinical data before and after

[5] Although the Court need not address the issue, to the extent that Plaintiffs rely on *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668 (2019), to argue that Pfizer itself was required to propose a labeling change that is later rejected by the FDA, they are incorrect. In *Merck*, the Supreme Court explicitly declined to specify the "methods" by which the FDA must disapprove of a labeling change to trigger preemption. *Id.* at 1679. Significantly, Justice Alito, joined by Chief Justice Roberts and Justice Kavanaugh, clarified in a concurring opinion in *Merck* that preemption "does not depend on whether ***the relevant drug manufacturer, as opposed to some other entity or individual***, brought the new information to the FDA's attention." *Id.* at 1684 (Alito, J., concurring) (emphasis added). Nor does it "require the FDA to communicate . . . that a label change is unwarranted." *Id.* Instead, "if the FDA declines to require a label change despite having received and considered information regarding a new risk . . . the FDA [has] determined that a label change was unjustified." *Id.* Courts have subsequently followed Justice Alito's concurring opinion. *See, e.g.*, *Cerveny v. Aventis, Inc.*, 2019 WL 3763441, at *3 n.9 (10th Cir. Aug. 9, 2019); *Roberto*, 2019 WL 5068452, at *23.

the 2012 label change (PAC ¶ 45; *see also* Def.'s Mot. at 4 n.2), and they fail to meet their burden to plead facts that could plausibly show "newly acquired information."[6] Plaintiffs' speculation about "what information was in the possession of" Pfizer (Opp. at 7), does not "unlock the doors of discovery" absent plausible factual allegations that information sufficient to warrant a label change even exists. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *see also Utts*, 251 F. Supp. 3d at 673. Pfizer thus is entitled to dismissal with prejudice of these facially deficient claims.

III. PLAINTIFFS' PRE-APRIL 2016 CLAIMS ARE TIME-BARRED

Plaintiffs do not offer any substantive response to Pfizer's arguments that claims that accrued prior to April 2016 are barred by the statute of limitations, but instead rest entirely on their request for amendment. (Opp. at 12.) They make no attempt, however, to show that their PAC would cure the timeliness problems with their original claims. Indeed, the PAC is subject to precisely the same problems as the Complaint and fails for the same reasons. Here too, amendment should be denied as futile. *See Chunn*, 916 F.3d at 208.

Even in the PAC, Plaintiffs do not plead the dates on which their claims accrued—that is, the dates on which they were each diagnosed with diabetes. *See* CPLR 214-c(2). Nor do they plead any fraudulent conduct by Pfizer that prevented them from discovering their claims within three years of that date, much less plead such conduct with the particularity required by Rule 9(b). Instead, their sole attempt to save the timeliness of their claims in the PAC is their conclusory invocation of the limited exception provided by CPLR 214-c(4). Despite the fact that Plaintiffs' counsel has filed nearly identical actions throughout this period, Plaintiffs allege that "[d]espite some information available to the general public concerning the ***question*** as to whether [Lipitor]

[6] To the extent that Plaintiffs suggest that they do not have access to new information because Pfizer allegedly hid data from the FDA (PAC ¶ 86), that fraud-on-the-FDA theory is itself preempted. *See Buckman Co. v Pls.' Legal Comm.*, 531 U.S. 341, 353 (2001).

can cause or contribute to diabetes," the alleged association "was not generally accepted in the science community" "through the time of the [MDL] Court's [*Daubert*] ruling." (*See* PAC ¶¶ 97–100.) They say "it would have been difficult, if not impossible, for Plaintiffs to have determined that Lipitor more likely than not increases the risk of diabetes, particularly in light of Pfizer's denials of such a relationship." (*See id.*) This cannot save their pre-April 2016 claims from dismissal.

First, even if the Court were to accept these conclusory allegations, they would not save Plaintiffs' claims. The very earliest claims to which this theory could potentially apply would be those that accrued after March 2014, and only if the alleged causal relationship could not have been identified until April 2018 or later. *See* CPLR 214-c(4) (requiring plaintiff to bring claim within five years of discovery of injury and within one year of discovery of cause of injury). Because all such claims accrued after 2012, they would be preempted for the reasons stated above.

Second, just as the PAC fails to plead "newly acquired information," it also fails to plead any scientific knowledge that arose in April 2018 or afterward that Plaintiffs claim gave them sufficient cause to file their claims, as they are required to do in response to Pfizer's statute of limitations defense. *See id.* (requiring plaintiff to "allege and prove" that medical knowledge was not available prior to expiration of limitations period and that she acted with reasonable diligence in discovering her injuries). The absence of any plausible factual basis to support that assertion is fatal to the timeliness of Plaintiffs' pre-April 2016 claims.

CONCLUSION

For the foregoing reasons and those set forth in prior briefing, the Court should grant Pfizer's Motion for Judgment on the Pleadings, deny Plaintiffs' requests to amend the Complaint and for additional time to respond, and dismiss the Complaint with prejudice in its entirety.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 13, 2019, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which sends electronic notification of such filings to all CM/ECF participants.

/s/ Mark S. Cheffo
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